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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Cincinnati District

Redacted

Food & Drug Administration
1141 Central Parkway
Cincinnati, OH 45202-1097

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

June 26, 1998

Warning Letter
CIN-WL-98-313

Herbert Hoebel, President
First Lafayette Holding Company
Yorba Linda, California
c/o Joseph LaPalomento, General Manager
Victoreen, Inc.
6000 Cochran Road
Cleveland, Ohio 44139

Re: Victoreen, Inc.
600 Cochran Road
Cleveland Ohio 44139

Dear Mr. Hoebel:

During an inspection of your firm, Victoreen, Inc. located at the above address on May 12-20, 1998 our Investigators determined that your firm manufactures a variety of diagnostic and therapeutic radiation detection products including Veridose Diodes . These products are devices as defined by Section 201(h) of the Federal Food, Drug and Cosmetic Act (the Act). The Inspection revealed that your devices are adulterated in that, the methods used in, or the facilities or controls used for manufacturing, packaging, storage, or installation are not in conformance with the Quality System Regulation (QSR) for Medical Devices specified in Title 21, Code of Federal Regulations (CFR), Part 820, as follows:

Failure to ensure that the disposition process for nonconforming products is adequately controlled. The determination to use nonconforming components in production is not always based on scientific evidence. Concessions for using nonconforming components are not closely monitored and there is no assurance that the use of non conforming components has not become accepted practice.

> From December 2, 1996 to November 7, 1997 numerous components were accepted without the proper inspections. The concession to accept components without the proper inspections was done based on a 12/2/96 memo from an employee in purchasing in order to eliminate a backlog in receiving. The SOP #910.30, general inspection procedure for incoming materials was not followed and there was no record that the change in the inspection procedure was authorized, i.e. a document change record as required by your firm's SOPs for change control.

> Part # 30-472-2 (build-up caps used in the Veridose Diodes) was not inspected in accordance to established inspection procedures. This part was delivered to stock without inspection as specified in the inspection instructions due to a mistaken belief that the part was still under R & D control. This mistake resulted in the use of improper build-up caps in Veridose Diodes manufactured between December 2, 1996 to November 7, 1997.

Failure to establish and maintain procedures for rework to include retesting and reevaluation of the nonconforming product after rework, to ensure that the product meets its current approved specifications.

> When a Veridose Diode is manufactured there are three inspections conducted which include a first functional test prior to injection molding. If the diodes fail the first functional test, they are returned to manufacturing for rework. There are no records maintained of the disposition for rework of the diodes or documentation that the diodes failed the first functional test.

This letter is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to assure adherence to each requirement of the ACT and regulations. The specific violations noted in this letter and in the FDA 483 issued at the closeout of the FDA inspection may be symptomatic of serious underlying problems in your firm's manufacturing and quality assurance systems. You are responsible for investigating and determining the causes of the violations identified by the FDA. If the causes are determined to be systems problems you must promptly initiate permanent corrective actions.

We acknowledge that you have submitted to this office a response concerning our investigators observations noted on the form FDA 483. We reviewed you response and have concluded that it is adequate to correct the FDA 483, item #5 regarding identifying training needs to ensure all personnel are trained appropriately.

However, the FDA 483, items # 1-4 all appear to relate to lack of adequate control of the use of non conforming products. To date this problem has resulted in two recalls by your firm. In particular, your response to FDA 483, item #1 pertaining to the rework of Veridose Diodes that fail the first function test prior to injection molding was not adequate. You stated that due to the nature of the products, a Nonconforming Materials Report (NCR) for each item not meeting specifications at this level would result in an impractical amount of documentation for the technician. Rework and reevaluation activities, including a determination of any adverse effect from the rework upon the product should be documented in the device history record.

The FDA inspection revealed that the ownership and management of Victoreen, Inc. has changed since the last FDA inspection of your firm. Therefore, in order to facilitate FDA in making the determination that QSR corrections have been made and thereby enabling FDA to withdraw its advisory to other federal agencies concerning the award of government contracts, and to resume marketing clearance, and export clearance for products manufactured at your facility, we are requesting that you submit to this office on the schedule below, certification by an outside expert consultant that it has conducted an audit of your firm's manufacturing and quality assurance systems relative to the requirements of the device QSR regulation (21 CFR, Part 820). You should also submit a copy of the consultant's report, and certification by your firm's CEO (if other than yourself) that he or she has reviewed the consultant's report and that your firm has initiated or completed all corrections called for in the report. The attached guidance may be helpful in selecting an appropriate consultant. The initial certifications of audit and corrections and subsequent certifications of updated audits and corrections (if required) should be submitted to this office by the following dates: November 20, 1998, November 19, 1999, and November 20, 2000.

Federal agencies are advised of the issuance of all warning letters about devices so that they may take this information into account when considering the award of contracts. Additionally, no premarket submissions for devices to which the QSR deficiencies are reasonably related will be cleared until the violations have been corrected. Also, no requests for Certificates For Products For Export will be approved until the violations related to the subject devices have been corrected.

You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action being initiated by The Food and Drug Administration without further notice. Possible actions include, but are not limited to , seizure, injunction, and/or civil penalties.

Please notify this office in writing within fifteen (15) working days of receipt of this letter, of the specific steps you have taken to correct the noted violations, including an explanation of each step being taken to prevent the recurrence of similar violations. If corrective action cannot be completed within fifteen (15) working days, state the reason for the delay and the time within which the corrections will be completed.

Your response should be sent to Evelyn D. Forney, Compliance Officer, Food and Drug Administration, 1141 Central Parkway, Cincinnati, Ohio 45202.

Sincerely,

Charles William Sedgwick
Acting District Director
Cincinnati District

Attachment: "Selecting a Consultant?"

cc: Joseph LaPalomento,
General Manager
Victoreen, Inc.